Surgeon Dominated Design Can Improve the Accuracy of Patient-specific Instruments in Kinematically Aligned TKA

Zhiwei Wang  
Beijing Chaoyang Hospital

Liang Wen (wenliang@ccmu.edu.cn)  
Beijing Chaoyang Hospital

Liang Zhang  
Beijing Naton Medical Technology Innovation Center

Desi Ma  
Beijing Chaoyang Hospital

Xiang Dong  
Beijing Naton Medical Technology Innovation Center

Tiebing Qu  
Beijing Charity Hospital

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Abstract

Precise bone resection is mandatory for kinematically aligned total knee arthroplasty (KA-TKA). Patient-specific instrumentation (PSI) has been applied to improve the accuracy of bone resection in TKA for many years. The purpose of this study was to investigate whether surgeons’ domination in PSI design can improve accuracy in KA-TKA. A total of 24 patients (24 knees) who underwent KA-TKA in our institution were assigned into engineer designed PSI group (10 knees) and surgeon designed PSI group (14 knees). The bone resection discrepancies of every key facets were used to evaluate the accuracy of PSI in bone resection, while the absolute differences of joint line orientation before and after surgery were used to evaluate the accuracy of PSI in joint line restoration. The overall discrepancy of bone resection was reduced by surgeon designed PSI compared to engineer designed PSI by 0.33mm (P<0.001). Surgeon designed PSI could reduce the outliers in terms of relative discrepancies in bone resection as well. Moreover, surgeon designed PSI could significantly improve the accuracy of PSI in the restoration of the joint line (p=0.01). This study indicate that the dominance of surgeons in both PSI design and subsequent surgical operation should be emphasized in efforts to improve the accuracy of PSI.

Introduction

The alignment target of kinematically aligned total knee arthroplasty (KA-TKA) is to restore the articular geometry of tibia-femoral joint and the pre-arthritic joint laxity, while abandon the neutral coronal alignment of mechanical alignment (MA)\(^1\). Many studies had shown that KA has advantages in restoring knee kinematics\(^2,3\), improving patients’ satisfaction\(^4\), reducing soft tissue disturbance\(^5\), and a promising mid-term survival rate of implants\(^6\).

As a three dimensional alignment method, KA has strict requirements for bone cutting accuracy\(^4,7\), a variety of computer-aided alignment tools, such as patient-specific instrumentation (PSI), navigation and even robotic assistant surgery, were used to improve the accuracy of bone resection and components implantation\(^8-12\). PSI plays the role of positioning tools or jigs, which help in executing surgeries with more accuracy, lesser operative time and minimal invasive purposes. Although PSI has been popularized in TKA for years\(^13\), there is no consensus on its actual values in terms of accuracy, reliability or feasibility\(^14-21\).

Many factors may impact the accuracy of PSI, including the error of the preoperative landmarking on the 3D model during the design phase, medial parapatellar approach, ambiguous positioning of the PSI on the cortex, sawing error, final impaction of components, the experience of the surgeons, the quality of medical images for postoperative assessment, and so on\(^22\). Only a few studies mentioned the role of surgeons in the PSI design process\(^23,24\). Since the alignment target of KA-TKA is not in accordance with neutral coronal alignment, participation of surgeons in the design of each PSI may be more conducive to ensuring its accuracy. The purpose of this study is to investigate whether surgeons’ domination in PSI design can improve accuracy in KA-TKA.

Methods

In this retrospective study, a prospectively managed medical record database and corresponding medical imaging database were queried. A total of 24 consecutive patients (24 knees) undergoing primary KA-TKA assisted with PSI between May 2018 and December 2019 at a single institute were investigated. Engineer designed PSIs were used in the first 10 knees, while surgeon designed PSIs were employed in the other 14 knees. Approval was granted by the Ethics Committee of Beijing Chaoyang Hospital(#2015-S-004) in this study, written informed consent was obtained from all individual participants, and all methods of this study were performed in accordance with the regulations of retrospective clinical research in our institution. Patient demographics were summarized in Table 1.

Patient selection

All patients were meticulously selected according to the following inclusion criteria: knee osteoarthritis (OA) with grade I or grade II of Kellgren-Lawrence classification, OA-related symptoms were inert to various conservative measures, hip-knee-ankle (HKA) angle \(\leq 12^\circ\) and medial proximal tibial angle (MPTA) \(\geq 85^\circ\) in varus knees, \(\leq 5^\circ\) of valgus knee with no medial collateral ligament (MCL) dysfunction or posterior condyles dysplasia. Exclusion criteria: patients with prior trauma or knee surgeries, inflammatory arthritis,
> 20° of flexion contracture, obvious bone defect or deformities, posterior cruciate ligament (PCL) dysfunction, and patellar instability.

**Design and manufacturing of PSI**

In this study, the design and manufacturing of all PSIs were based on full-length computed tomography (CT, Slice thickness, 0.625mm) of lower extremities. It was mandatory to compensate for the thickness of the articular cartilage by 2mm in the CT-based PSI design. Articular surface-based rather than tibio-femoral flexion axis-based PSI design was employed in this study.

On the femoral side, the distal and posterior facets of medial and lateral femoral condyles must be resurfaced by femoral components. The sizes of femoral components were determined according to the antero-posterior (AP) dimension of femoral condyles. On the tibial side, the resected medial and lateral tibial plateau should be replaced by tibial component and polyethylene insert, rotational alignment of tibial component was determined by the connection line between the insertion of PCL and medial border of tibial tubercle (TT), and posterior slope of tibial resection was in accordance with the natural posterior slope of medial plateau, the size of tibial component was determined by the best fit of virtual resection surface.

NX 9.0 (Siemens PLM Software, TX, US) was used for the design of PSI (Figure 1). Rapid prototyping technology (Formiga P 110, EOS, Krailling, Germany) was used for 3D printing of the PSI. The printing material is medical nylon (PA2200 Polymer powder, EOS, Krailling, Germany).

**Grouping of patients**

The design of the first 10 SPIs (engineer group) were accomplished by the engineers according to the above design philosophy. In the subsequent 14 knees (surgeon group), surgical operators comprehensively participated in the design of PSI through an application (EZguide™, Naton Medical Technology Innovation Center, Beijing, China) developed by coauthors in this study (ZL, XD).

The advantage of this App is that the surgeon can adjust the prosthetic components in 6 degrees of freedom according to the technical requirements of different alignment (Figure 2). Moreover, the confirmed design protocol can be brought into the operating room via a portable device, making the intraoperative verification of the accuracy of PSI as easy as querying the patient's radiograph through PACS integrated in operating room. Intraoperative verification is to confirm the consistency between the preoperative design and the intraoperative measurement and observation in terms of the geometry and thickness of the excised bone fragments and the shape of the bone cutting surface(Figure 3).

**Intraoperative positioning of PSI**

The CT-based PSI doesn't take account for the thickness of residual articular cartilage which should be removed by using a special curette before the PSI is secured to its unique position. In addition, the periosteum on the anterior aspect of the distal femur and on the medial-proximal aspect of the tibial tubercle should also be completely removed and all osteophytes should be kept in place so that the PSI can sit on the bony surface firmly and accurately. In this study, PSI was used for positioning of the key locating pins instead of providing the slots for saw blade. When the locating pins were in place, PSI was removed and conventional cutting block was seated in line with the locating pins.

On the femoral side, before the securing of femoral PSI, compare the gap between PSI and print bone with that between PSI and the native distal femur (Figure 4). The geometry of this gap is very sensitive to the rotation of the PSI on the sagittal plane, and it is critical to reduce the incidence of less accuracy in posterior femoral condyle cuts which had been reported in a published literature. On the tibial side, draw a line through tibial spine perpendicular to the articular surface of the tibial plateau on the full-length radiograph, then the radiograph with reference lines was brought into the operating room. Before the securing of tibial PSI, Use the extra-medullary alignment rod affiliated with PSI to verify whether its orientation is consistent to that of the radiograph (Figure 5). Posterior cruciate retained (CR) prostheses (Gemini MK, Link, Hamburger, Germany) were used in this study.

**Assessment of the accuracy of PSI**
The assessment of the accuracy of PSI mainly included two sets of parameters: the discrepancies of bone resection and the changes of joint line orientation. As far as the discrepancy of bone resection is concerned, the bone resection of each key facet was measured by caliper and recorded, and was compared with the thickness of components after compensation of cartilage (2mm) and kerf of the saw blade (1.5mm). This discrepancy is defined as positive when the actual resection thickness is larger than the component’s one, otherwise it is defined as negative. As far as the changes of joint line orientation is concerned, mechanical lateral distal femoral angle (mLDFA) and medial proximal tibial angle (MPTA) were used as assessment parameters. Compare the joint line parameters measured before and 3 months after the operation (Figure 6). Any intraoperative additional bone cut or ligament release, defined as out of plan manipulation, were recorded as well (Table 1).

Statistical analysis.

Data distribution of all measurement parameters were assessed by the Kolmogorov-Smirnov test. Normal distributed variables were presented as mean±standard deviation, while attribute data was presented with absolute number. The independent samples t test was used to compare the variable data of patient demography between engineer group and surgeon group, General linear model and multivariate analysis of variance (ANOVA) were used to explore the effects of PSI types (engineer group, surgeon group), side (medial, lateral), and resection facets (distal femur, posterior condyle, tibial plateau) on the accuracy of bone cut. Similarly, the effects of PSI types and side (femoral side: mLDFA, tibial side: MPTA) on the restoration of joint line were investigated using multivariate analysis of variance. The outliers of each measurement parameters were presented as free points in the box plots. Neither sample size calculation nor test power estimation was performed in current study. All data analyses were conducted using SPSS (version 22.0, Chicago, IL, USA). The level of significance (p value) was set at 0.05.

Results

**Descriptive statistics of patient demographics.** No significant difference in terms of age, BMI or operative time was shown between engineer group and surgeon group. Due to the small sample size of this case series, other attribute data had not received any further statistical calculation, and were only presented in absolute numbers (Table 1). All patients did not receive medial collateral ligament or lateral ligament structure releasing in our study. 4 patients received lateral patellar retinaculum releasing, 3 patients received a 2 mm of manual extra-cut on the medial tibia plateau, and +2 mm thicker liner was used in 2 patients.

**Accuracy of bone resection.** The effects of three independent variables, including PSI type, facets and side, on the bone resection difference were shown in Table 2. The results of multivariate ANOVA showed that the main effects of PSI type and facets on the difference of resection were significantly different (p<0.001), while side had no significant effect on the difference of resection (p=0.608). The gross difference of bone resection was reduced by surgeon designed PSI compared to engineer designed PSI by 0.33mm (p<0.001). The bone resection differences of two PSI types in different facets were shown in Figure 7 (a, b, c). In the subsequent pairwise comparisons of different facets, the resection of tibial plateau was found 0.43mm thinner than that of the distal femur (p<0.001), and 0.68mm thinner than that of the posterior condyle on average (p<0.001). The resection of posterior condyle was 0.25mm thicker than that of the distal femur on average (p=0.029). Besides that, surgeon designed PSI could reduce the outliers in terms of relative discrepancies in bone resection (Figure 7, a, b, c).

**Accuracy of joint line restoration.** When the effects of different PSI types on the restoration of joint line were investigated, absolute deviations were used as the dependent variables. The results of multivariate ANOVA demonstrated that surgeon designed PSI significantly improve the gross accuracy in the restoration of the joint line (p=0.01), but no significant difference was found between the femoral side and the tibial side (p=0.466) (Table 3, Figure 7, d).

Discussion

The results of this study demonstrated that surgeon's participation in preoperative design can significantly improve the accuracy of PSI in terms of bone cutting accuracy and joint line reconstruction. In this study, a self-developed surgeon-engineer interactive application allows surgeon to fully participate in the design of PSI. The surgeons has the authority to adjust all design parameters, including adjusting the position of the femoral component and tibial component in 6 degrees of freedom, and changing the size of...
the components. This application combined with intraoperative verification has significantly enhanced the accuracy of PSI in KA-
TKA. Moreover, the sizes of implanted components matched up with the preoperative designed ones in all knees.

In the design of PSI, what role the doctor should play is an interesting topic. A survey demonstrated that although most surgeons have shown great interest in the application of PSI in TKA, 47% of surgeons believed that it was the manufacturer's fault if PSI is not accurately aligned in the operation. However, the absence of the participation of the surgeon may be one of the important reasons for the inconsistent results of PSI accuracy. Pietsch et al. found that surgeon's participation in preoperative PSI design could make preoperative planning more accurate and significantly reduce the intraoperative adjustments, but only a few design parameters, including femoral flexion, component sizes and tibial rotation, were allowed to be adjusted by the surgeons in their study.

The accuracy of PSI is also affected by other factors. For example, PSI designs are based on a three-dimensional graph models, which are obtained by computed tomography (CT) or magnetic resonance imaging (MR) reconstruction. Although many studies have shown that MR based PSI is more accurate than CT based one, the latter has many advantages, such as quick access, cheap, automatic software based reconstruction, etc., and more importantly, easier to obtain thinner slices (0.625mm in this study), which is critical for reproducing the anatomical articular details. After weighing the pros and cons, CT based PSI with better cost-effectiveness was applied in this study.

Other studies dedicated to increasing the accuracy of PSI are mainly to improve the design, especially the design of the tibial PSI. A large number of studies have confirmed that PSI has advantages in improving the alignment of the femoral component and global mechanical alignment, but with an increased risk of outlier for the tibial component alignment. In current study, in order to improve the accuracy of the tibial PSI, an extended cannula to accommodate alignment rod was employed to verify the accuracy of the PSI installation as per Yamamura's method. Even so, the results of this study found that the accuracy of the tibial cut is slightly inferior to that of the femoral cut, which is mainly manifested in the greater dispersion and more outliers of the tibial cut data. Surprisingly, surgeon's participation in the preoperative PSI design can further reduce such tibial cut errors, and it has a significant advantage in eliminating outliers. This may be attributed to the visual surgeon-engineer interactive application, which can assist surgeons in executing intraoperative bone cut verification. The highlighted bone cut fragments on the application interface makes it easy to identify outliers when using angel wing for double check.

Some results of this study need additional explanation. The PSI used in this study showed the tendency of a slightly thicker posterior condylar resection and distal femoral resection, while showed a tendency of a slightly thinner proximal tibial resection. This tendency is not sort of systematic errors, but we deliberately did it in the PSI design process. Because the polyethylene insert of the Gemini CR prosthesis is a deep dish like design with an elevated posterior edge, if the posterior femoral condyles were equally replaced, the flexion gap would be too tight.

There were several limitations in this study. First, current study is not a randomized controlled design. The objects are enrolled into engineer group and surgeon group according to the chronological sequence of receiving TKA. Therefore, it is reasonable that the learning curve of PSI would affect the results of this study. Because our research group had used the exact same commercial PSI for many years, the adverse effects of the learning curve could be significantly diminished. Secondly, the sample size of this study is small, but this study can still draw the conclusion that surgeon's participation in the design can significantly improve the accuracy of PSI.

In conclusion, the contribution of the surgeons in the design process of PSI was strengthened further in this study. If a surgeon dominated the design process of PSI and surgical operation one after another, the intraoperative positioning and fixation of PSI would be more in line with the preoperative planning, so the accuracy of PSI could be significantly improved as well. A portable surgeon-engineer interactive application makes it more feasible for surgeons to participate in PSI design and intraoperative bone cut verification.

Declarations

Acknowledgements
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**Author contributions**

LW and ZW were responsible for the design of the study. Surgical operations were performed by ZW, LW and DM. The print of PSI was completed by LZ and XD. Data collection and analysis were performed by ZW and DM. The first manuscript was drafted by ZW and revised by LW, DM and TQ. All authors read and approved the final manuscript.

**Additional information**

**Competing interests**

TQ has received research grants from National Natural Science Foundation of China (NSFC, 81572180), other authors declare no competing interests.

**Data availability**

The datasets used or analyzed in this study are available from the first author or corresponding author on reasonable request.

**References**


**Tables**

Table 1 Preoperative patient demographics and other parameters of engineer designed PSI group and surgeon designed PSI group.
Table 2 Bone resection discrepancies (mean±SD) between the preoperative PSI design and intraoperative actual measurements

<table>
<thead>
<tr>
<th>PSI Group</th>
<th>Facet</th>
<th>Distal femur(mm)</th>
<th>Post. condyle(mm)</th>
<th>Tibial plateau(mm)</th>
<th>AVONA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Side</td>
<td>Medial</td>
<td>Lateral</td>
<td>Medial</td>
<td>Lateral</td>
</tr>
<tr>
<td>Engineer group</td>
<td></td>
<td>0.5±0.6</td>
<td>0.5±0.4</td>
<td>0.8±0.8</td>
<td>0.8±0.6</td>
</tr>
<tr>
<td></td>
<td>Side</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.1±0.3</td>
<td>0.1±0.3</td>
<td>0.4±0.5</td>
<td>0.2±0.5</td>
</tr>
<tr>
<td>Surgeon group</td>
<td></td>
<td>0.1±0.3</td>
<td>0.1±0.3</td>
<td>0.4±0.5</td>
<td>0.2±0.5</td>
</tr>
</tbody>
</table>

PSI patient-specific instrumentation, Post. condyle, femoral posterior condyle

Table 3 The effects of PSI on the absolute deviation of joint line orientation (mean±SD)
<table>
<thead>
<tr>
<th>PSI group</th>
<th>Side of joint line(deg.)</th>
<th>ANOVA (P value)</th>
<th>mLDFA</th>
<th>MPTA</th>
<th>PSI</th>
<th>Side</th>
<th>PSI*Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engineer group</td>
<td>1.40±1.18</td>
<td>1.78±1.44</td>
<td>0.010</td>
<td>0.466</td>
<td>0.576</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgeon group</td>
<td>0.77±0.66</td>
<td>0.82±0.71</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

PSI patient-specific instrumentation, mLDFA mechanical lateral distal femoral angle, MPTA medial proximal tibial angle